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Registration Decision RD2012-11

Pseudomonas fluorescens Strain A506

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Registration Decision for *Pseudomonas fluorescens* Strain A506

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale use of *Pseudomonas fluorescens* Strain A506 and BlightBan A506, containing the technical grade active ingredient *Pseudomonas fluorescens* Strain A506, to suppress fire blight caused by *Erwinia amylovora* on apples and pears.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-18, *Pseudomonas fluorescens Strain A506*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Pseudomonas Fluorescens* Strain A506 and summarizes the Agency's decision. The PMRA received no comments on PRD2011-18. This decision is consistent with the proposed registration decision stated in PRD2011-18.

For more details on the information presented in this Registration Decision, please refer to PRD2011-18, *Pseudomonas fluorescens Strain A506*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at http://www.healthcanada.gc.ca/pmra.

What is *Pseudomonas fluorescens* Strain A506?

Pseudomonas fluorescens strain A506 is a naturally occurring strain of bacterium that is used as a microbial pest control agent (MPCA) for the suppression of *Erwinia amylovora*, the pathogen that causes fireblight on apple and pear trees. BlightBan A506 is a commercial end-use product containing *Pseudomonas fluorescens* strain A506 as the active ingredient. *Pseudomonas fluorescens* strain A506 works by competitively excluding the pathogen for space and nutrients on branches and leaves and on blossoms.

Health Considerations

Can Approved Uses of *Pseudomonas fluorescens* Strain A506 Affect Human Health?

People could be exposed to *Pseudomonas fluorescens* strain A506 when handling and applying BlightBan A506. The PMRA considers several key factors when assessing health risks: the microorganism's biological properties (for example, production of toxic by-products), reports of any adverse incidents, its potential for pathogenicity, infectivity and toxicity as determined in toxicological studies as well as the likely levels to which people may be exposed to this strain relative to exposures already encountered in nature to other strains of this microorganism.

Pseudomonas fluorescens strain AGS 3001.2, a strain similar to *Pseudomonas fluorescens* strain A506, was found to be mildly irritating to the skin; therefore the precautionary words "CAUTION: Skin irritant " are required on the technical and end-use product label.

No other significant toxicity or signs of disease were observed in the toxicity studies submitted to support *Pseudomonas fluorescens* strain A506.

Residues in Water and Food

Dietary risks from food and water are not of concern

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

Strains of *Pseudomonas fluorescens* are common in nature. While the use of BlightBan A506 in orchards will lead to transient increases in populations, over the long-term, it is not expected to significantly increase natural environmental background levels of this microorganism. Furthermore, no significant adverse effects were reported when a mixture containing *Pseudomonas fluorescens* strain A506 and other *Pseudomonas* strains, or when *Pseudomonas fluorescens* strain AGS 3001.2, a strain similar to *Pseudomonas fluorescens* strain A506, was administered orally to rats.

Also, given that BlightBan A506 is applied to pome fruit trees at the flowering stage, *Pseudomonas fluorescens* strain A506 is not expected to come into direct contact with fruit, and consequently, the food use pattern is unlikely to result in significant residues on fruit at the time of harvest. Consequently, dietary exposure is minimal to non-existent, and the establishment of an MRL is not therefore required for *Pseudomonas fluorescens* strain A506. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling BlightBan A506

Occupational risks are not of concern when BlightBan A506 is used according to label directions, which include protective measures

Workers using BlightBan A506 can come into direct contact with *Pseudomonas fluorescens* strain A506 on the skin, in the eyes, or by inhalation. For this reason, the label will specify that users exposed to BlightBan A506 must wear waterproof gloves, long-sleeved shirts, long pants, a NIOSH approved respirator (with any N–95, R–95, P–95 or HE filter), and shoes plus socks. Early-entry workers will also be restricted from entering areas where BlightBan A506 has been applied for a period of 4 hours unless wearing the indicated personal protective equipment.

For bystanders, exposure is expected to be much less than that of workers involved in loading and application activities and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Pseudomonas fluorescens* strain A506 Is Introduced Into the Environment?

Please refer to Evaluation Report ERC2010-07 *Pseudomonas fluorescens* strain A506 for more information.

Value Considerations

What Is the Value of BlightBan A506?

BlightBan A506 is a powder formulation of *Pseudomonas fluorescens* strain A506 that is intended to be used for suppression of fire blight (*Erwinia amylovora*) on apples and pears.

BlightBan A506 is a new biological pesticide that may be used with Streptomycin 17, a bactericide currently registered for fire blight control which has important resistance management issues. BlightBan A506 is compatible with streptomycin and should be used in an integrated fireblight suppression program. Suppression of the fireblight pathogen, *E. amylovora*, with BlightBan A506 will help reduce grower reliance on streptomycin.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The PMRA is proposing key risk-reduction measures on the label of BlightBan A506, to address the potential risks identified in this assessment.

Key Risk-Reduction Measures

Human Health

Because of concerns with users developing allergic reactions through repeated high exposures to *Pseudomonas fluorescens* strain A506, anyone handling, mixing/loading, or involved in clean-up/repair activities of BlightBan A506 must wear waterproof gloves, a long-sleeved shirt, long pants and a dust/mist filtering respirator/mask (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator with any N-95, R-95, P-95 or HE filter.

Environment

Environmental risk mitigation measure can be found under Evaluation Report ERC2010-07 *Pseudomonas fluorescens* strain A506.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-18, *Pseudomonas fluorescens* strain A506) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.